


INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference<br>P104300WO   |  | <b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416) |  |
| International application No.<br>PCT/IB 03/04922   | International filing date (day/month/year)<br>29.09.2003 | Priority date (day/month/year)<br>27.09.2002   |  |
| International Patent Classification (IPC) or both national classification and IPC<br>A61K31/4985   |  |  |  |
| Applicant<br>SOCIETE DE CONSEILS DE RECHERCHES ET ...  |  |  |  |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>  |  |  |  |
| <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> |  |  |  |
| Date of submission of the demand<br><br>24.03.2004   |  | Date of completion of this report<br><br>11.11.2004  |  |
| Name and mailing address of the international preliminary examining authority:<br><br> European Patent Office - Glitschiner Str. 103<br>D-10958 Berlin<br>Tel. +49 30 25901 - 0<br>Fax: +49 30 25901 - 840  |  | Authorized Officer<br><br>Beyss, E<br><br>Telephone No. +49 30 25901-344   |  |



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/B 03/04922**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-49 as originally filed

**Claims, Numbers**

1-40 as originally filed

**Drawings, Figures**

1-6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
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International application No. PCT/IB 03/04922

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,  
☒ claims Nos. 26-33 with respect to industrial application

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):  
☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):  
☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.  
☒ no international search report has been established for the said claims Nos. 26-33 with respect to industrial application

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the Standard.  
☐ the computer readable form has not been furnished or does not comply with the Standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

|                               |             |             |
|-------------------------------|-------------|-------------|
| Novelty (N)                   | Yes: Claims | 2-40        |
|                               | No: Claims  | 1           |
| Inventive step (IS)           | Yes: Claims |             |
|                               | No: Claims  | 2-40        |
| Industrial applicability (IA) | Yes: Claims | 1-25, 34-40 |
|                               | No: Claims  |             |

2. Citations and explanations

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**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claims 26-33 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

D1: WO-A-0164197

D2: WO-A-0039130

The document D3 was not cited in the international search report. A copy of the document is appended hereto.

D3: British Journal of Cancer, vol. 87, no. 1, pages 15-20, 08.04.2002

**1. Novelty**

D1 describes formulations containing an anthracycline and a farnesyl transferase inhibitor according to formulas (I)-(IX) for the treatment of cancer (claims 1, 9, 12-14; formula (IX)).

D2 discloses farnesyl transferase inhibitors according to formula (I) of present application for the treatment of cancer (claims 1, 16).

D3 teaches about the efficacy of anthracyclins especially doxorubicin in cancer therapy (abstract).

Present application discloses formulations containing an anthracycline and a farnesyl

transferase inhibitor according to formula (I) for the treatment of cancer.  
The subject-matter of claim 1 of present application is not novel over the prior art.

## **2. Inventive Step**

D2 is considered to represent the most relevant state of the art. The problem to be solved by the present invention may therefore be regarded as the provision of a pharmaceutical formulation for the treatment of cancer.

The solution proposed in claims 2-40 of the present application cannot be considered as involving an inventive step. It is already known from the prior art that both compound per se namely doxorubicin (D3) as an anthracycline and a farnesyl transferase inhibitor (D2) according to formula (I) are effective in cancer treatment.

A farnesyl transferase inhibitor according to formula (I) is described in D2 as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include this feature in the pharmaceutical composition described in D3 in order to solve the problem posed.

Since the applicant has not shown that the combination of an anthracycline and a farnesyl transferase inhibitor according to formula (I) shows an unexpected surprising effect on cancer the subject-matter of claims 2-40 cannot be considered as involving an inventive step.

## **3. Clarity and Formal matters**

### **3.1.**

The formula (I) in claim 2 seems to be incorrect. The 5-membered ring should be an imidazol-ring. This can be corrected according to Rule 91 PCT.

### **3.2.**

Present claim 1 relates to the use of farnesyl transferase inhibitors. No further true technical characteristics of these compounds are given, but rather a definition by reference to a result to be achieved is attempted rendering the scope of said claim unclear (Art. 6

PCT).

**3.3.**

The term "heterocyclyl" used in claim 2 is vague and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claim unclear, Article 6 PCT.

**3.4.**

Claims 22-25 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved ("decreasing the rate of proliferation"), which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

**4. Industrial Applicability**

Claims 1-25, 34-40 meet the requirements of Article 33(4) PCT.